MAY - 4 2009

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

K083733

A. SUBMITTER INFORMATION:

Submitter's Name:	Lumenis, Inc.
Address:	3959 West 1820 South Salt Lake City, UT 84104
Contact:	Frances E. Harrison
Phone:	770-630-3281
Fax:	801-656-2627
Date of Preparation:	December 15, 2008

B. DEVICE NAME:

Trade Name(s):	Lume 2 System
Common/Usual Name:	Laser instrument, surgical, powered
Classification Names:	79 GEX, Laser Powered Surgical Instrument
CFR Reference:	21 CFR 878.4810, Laser surgical instrument for use in general and plastic surgery and in dermatology

C. PREDICATE DEVICE:

Lumenis One Family of Systems (K060448)

D. DEVICE DESCRIPTION:

The Lume 2 system is a multi-functional platform, computer controlled system which incorporates two technologies and two treatment heads: Intense Pulsed Light (IPL), and Nd:YAG Laser.
The Lume 2 console has a single treatment head connection port that accommodates either the Universal IPL or the Multi-Spot Nd:YAG treatment head.

The treatment heads are attached to the head connector via a flexible cable (umbilical). During operation, deionized water circulates from the system console through the umbilical cable to the treatment heads to cool the flashlamp assembly and/ or the laser head, and the umbilical cable also houses the power cable to provide energy to the light/laser emission and the electrical wiring to power the thermoelectric (TE) cooler. The energy is delivered in pulse sequences, to allow better control.

The principles of operation and fundamental scientific technology are the same for the subject devices and predicate device.

E. INTENDED USE:

The Lume 2, with Intense Pulsed Light (IPL) wavelengths 515-1200 nm, is indicated for the treatment of:

Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles) and tattoos.

Cutaneous lesions, including warts, scars and striae.

Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations, and

For the removal of unwanted hair from all skin types, an to effect stable long term, or permanent[1] hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

with Nd:YAG laser at wavelength 1064 nm, is indicated for:

The coagulation and hemostasis of vascular lesions and soft tissue, including the treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm. diameter) of the leg

The removal of unwanted hair from all skin types, an to effect stable long term, or permanent[1] hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

The non-ablative treatment of facial wrinkles.

[1] Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regimen.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY AND SUBSTANTIAL EQUIVALENCE STATEMENT:

The subject device, the Lume 2 system, has the same intended use, general design and fundamental scientific technology as the predicate device (K060448).

The Lume 2 system uses technology substantially equivalent to the Lumenis One Family of Systems (K060448). There are no new hazards introduced by the Lume 2 System as compared with the predicate devices.

G. PERFORMANCE DATA SUMMARY:

The appropriate testing including safety, performance and functional testing to determine substantial equivalence of the Lume 2 system has been conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2009

Lumenis, Ltd.
% Ms. Frances E. Harrison
Global VP, Regulatory Affairs/
Quality Compliance
3959 West 1820 South
Salt Lake City, Utah 84104

Re: K083733
Trade/Device Name: Lume 2 Intense Pulsed Light & Laser System and delivery devices
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 1, 2009
Received: April 3, 2009

Dear Ms. Harrison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): K083733

Device Name: Lume 2 Intense Pulsed Light & Laser System and delivery devices

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083733